

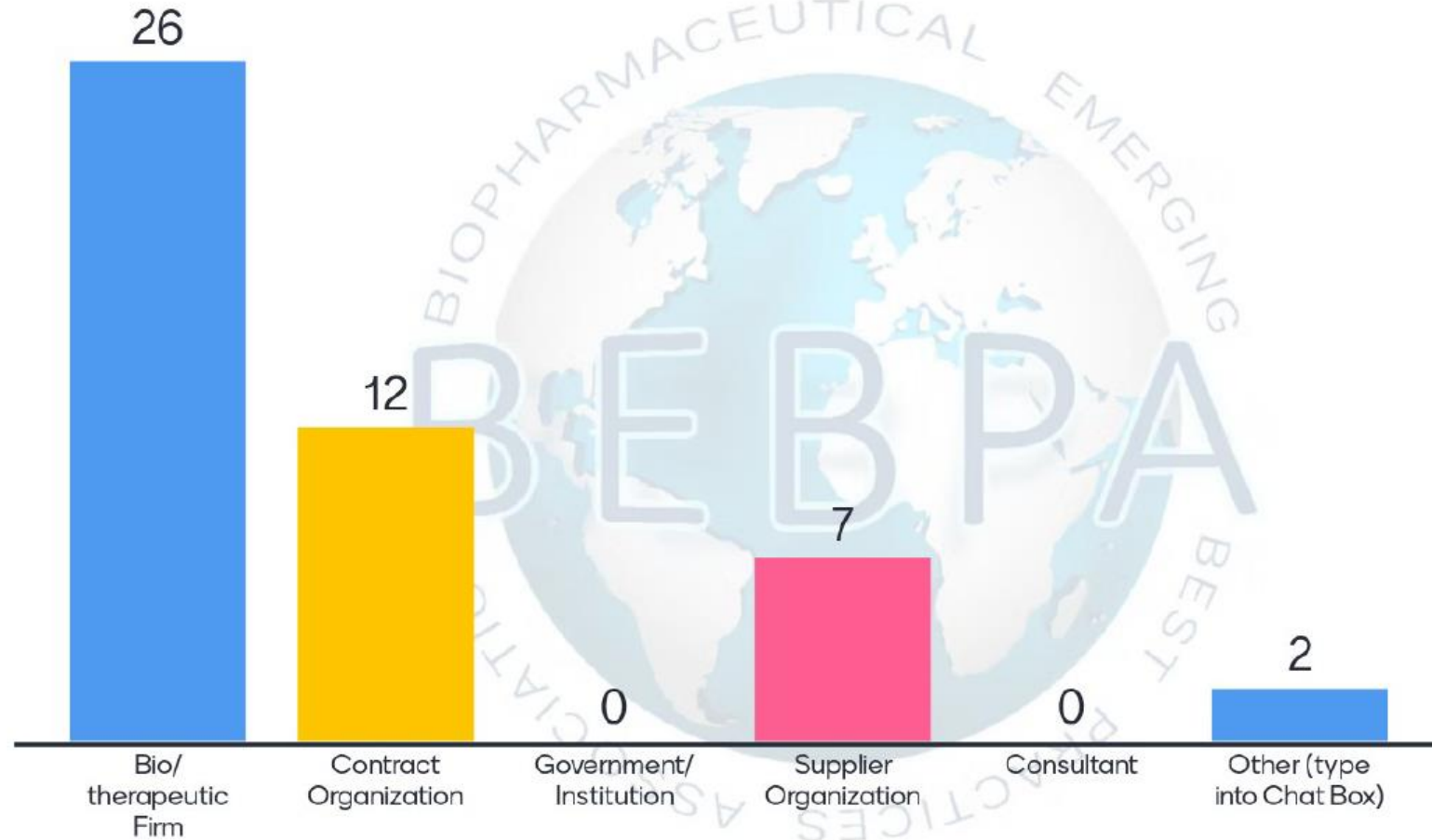
# Pre-Conference Workshop 2: Transferring Potency Assays

BEBPA 2022 EUR Bioassay Conference  
Tuesday, 27 September 2022

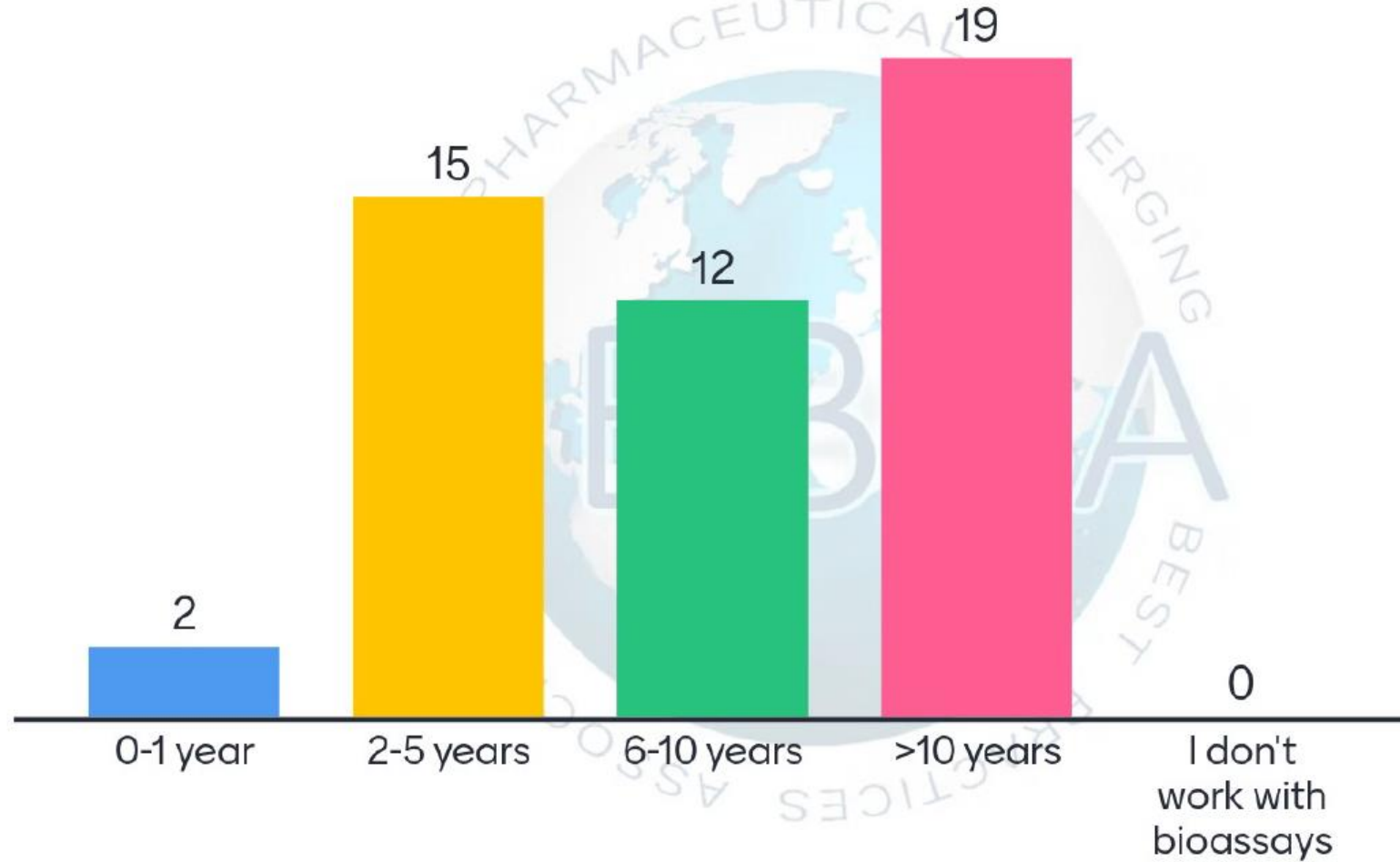
# Section 1 - Intro and General Information



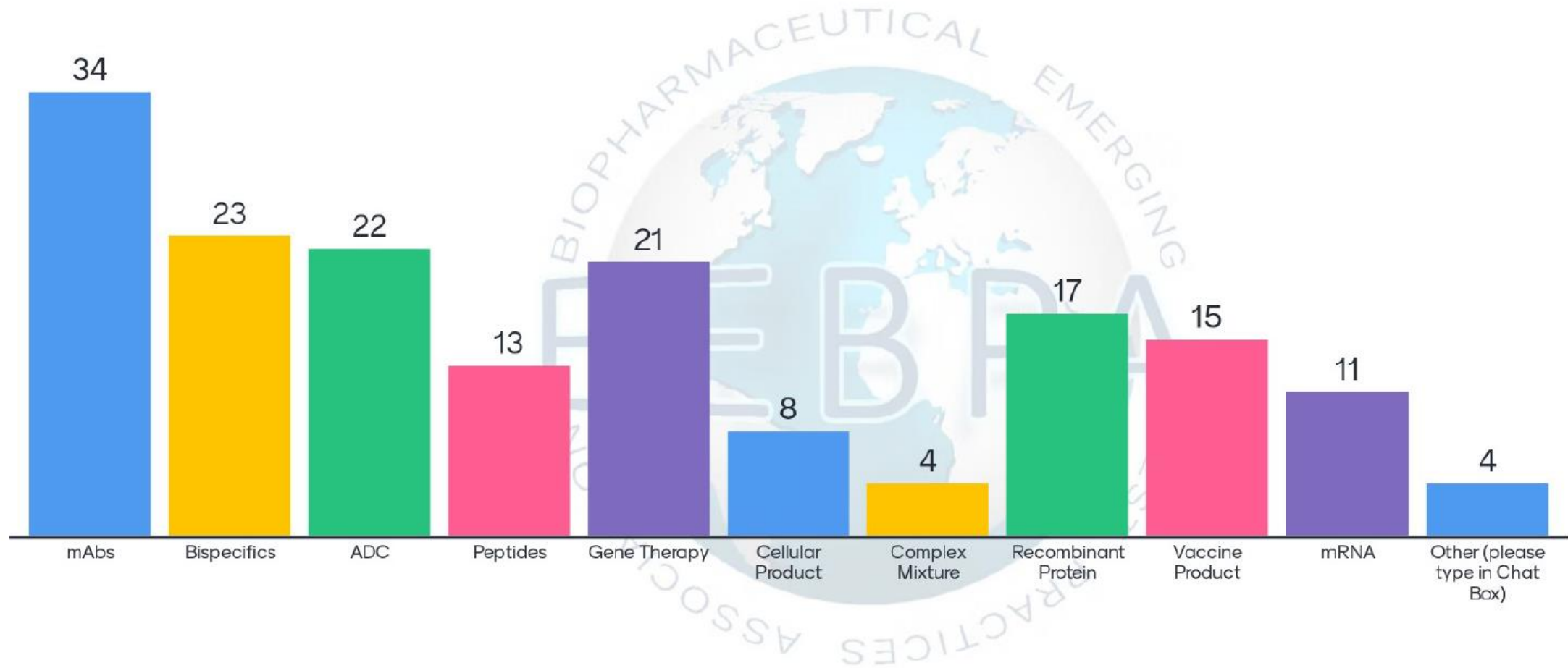
# 1.1 What kind of organization do you work with?



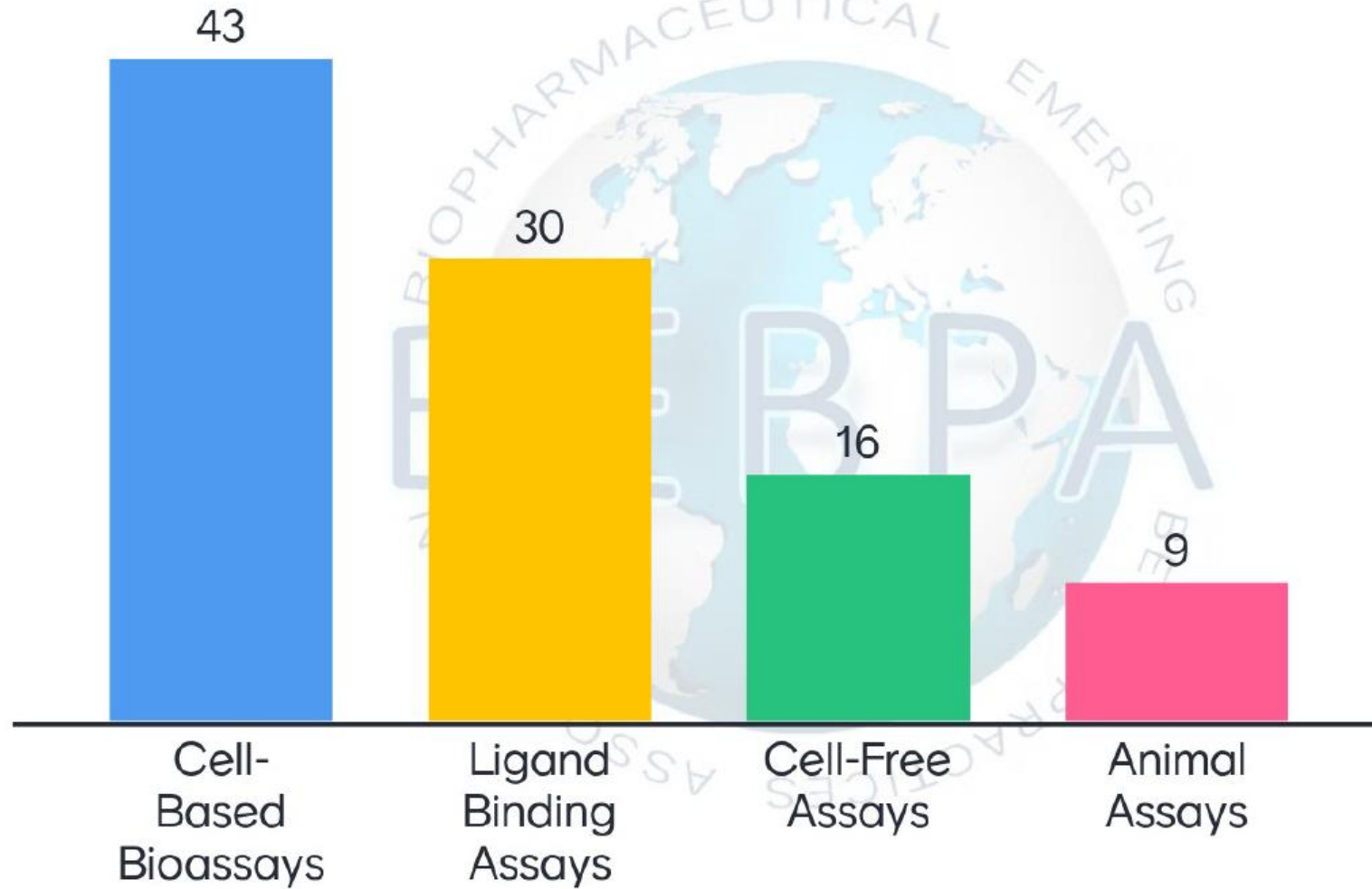
# 1.2 How long have you worked with bioassays?



# 1.3 What kind of products do you work with?

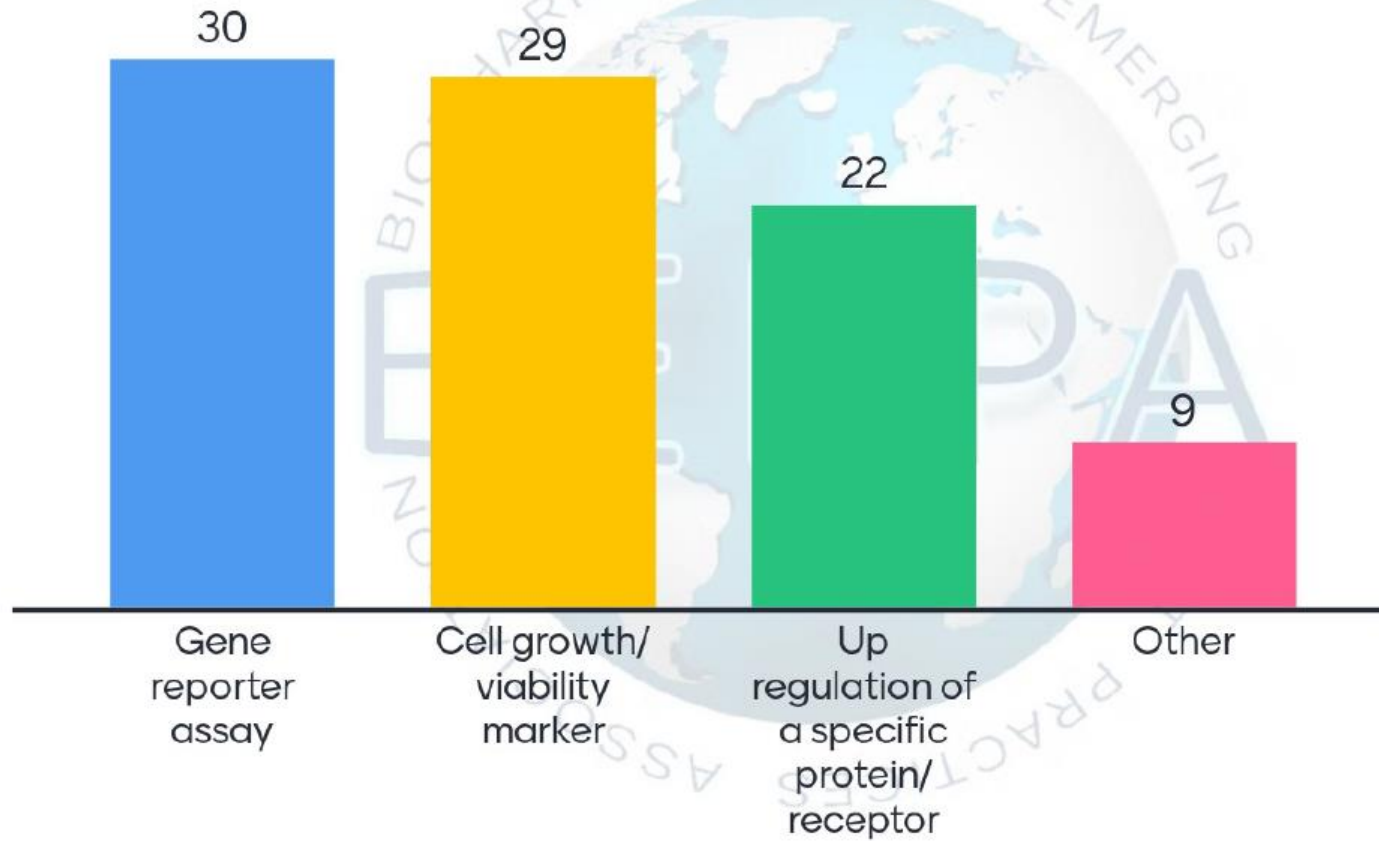


# 1.4 What kind of bioassays do you use?





# 1.5 For your cell-based assay, what readouts do you typically use?



# 1.6 If you answered other please type in a short description of the readout.



Enzyme activity

Enzymatic breakdown

Internalisation

Enzyme activity

Viability

Consumption of a cellular substrate

Viral copy numbers

Cell cycle

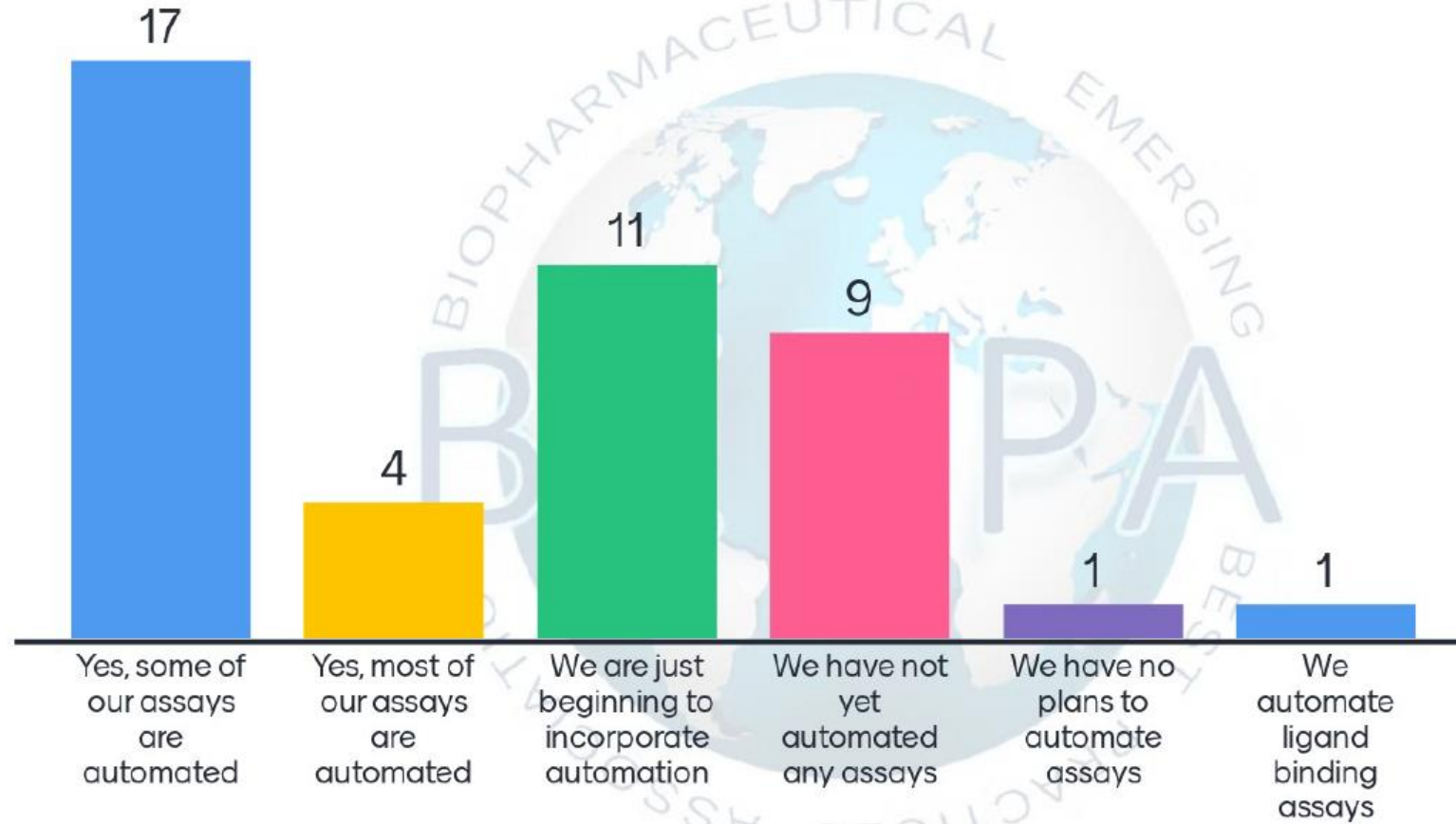
Internalisation, cytotoxicity

enzyme

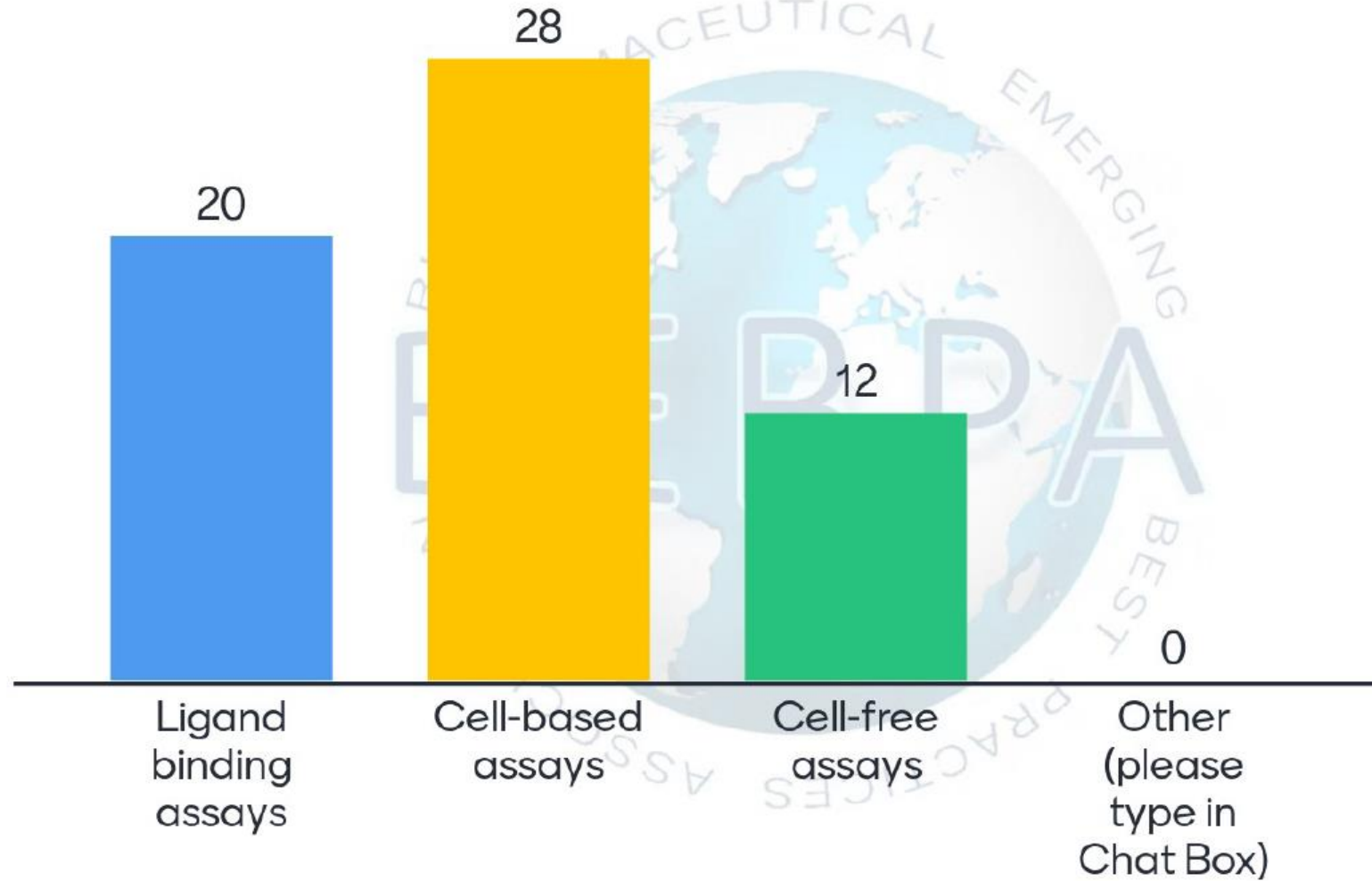
Receptor phosphorylation



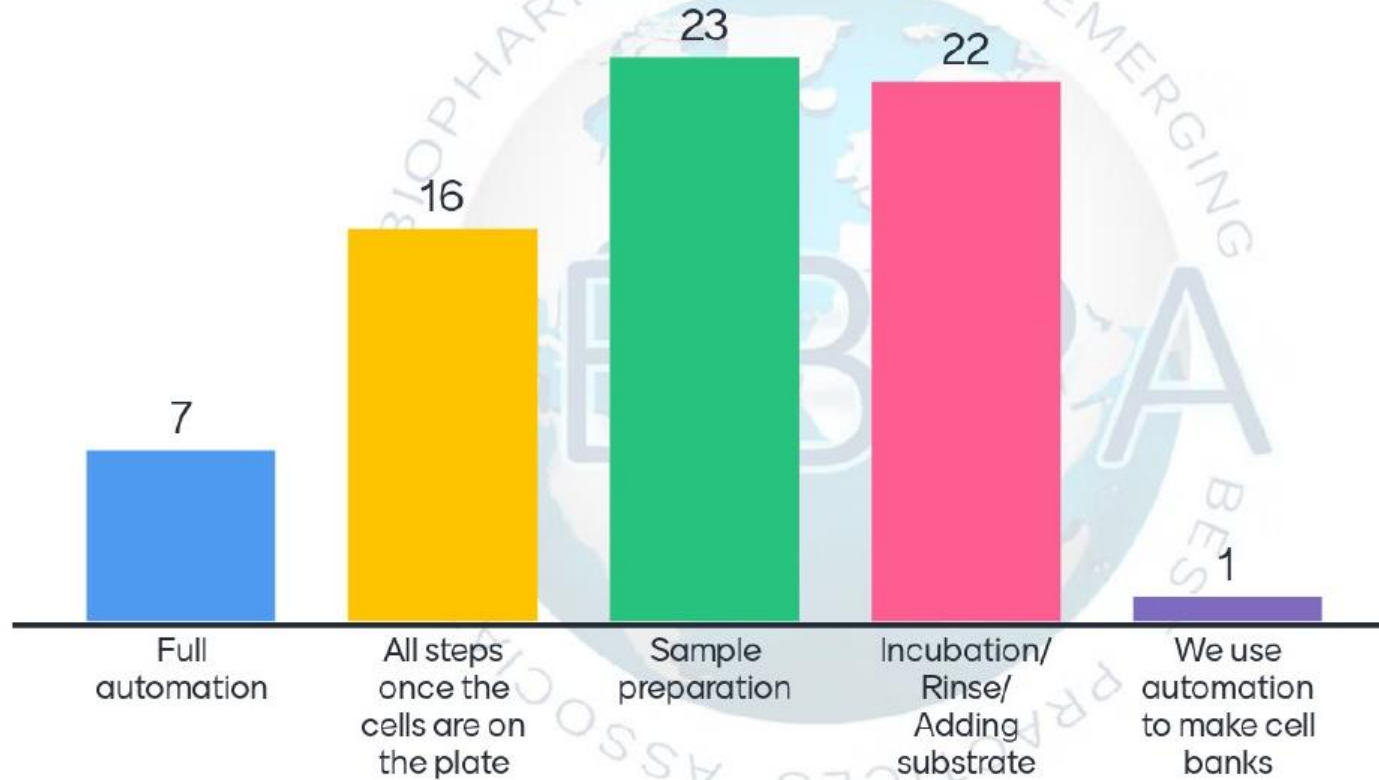
# 1.7 Do you use automation in your assays?



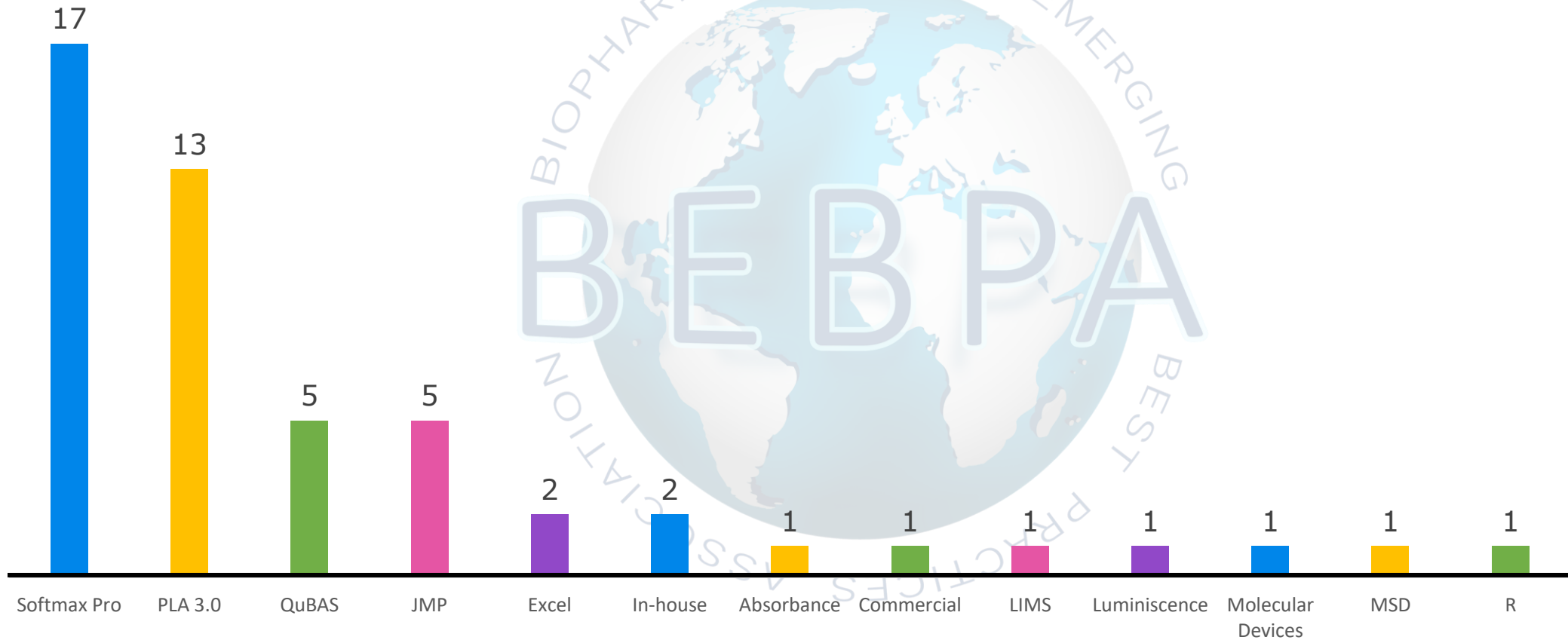
# 1.8 What type of assays do you automate?



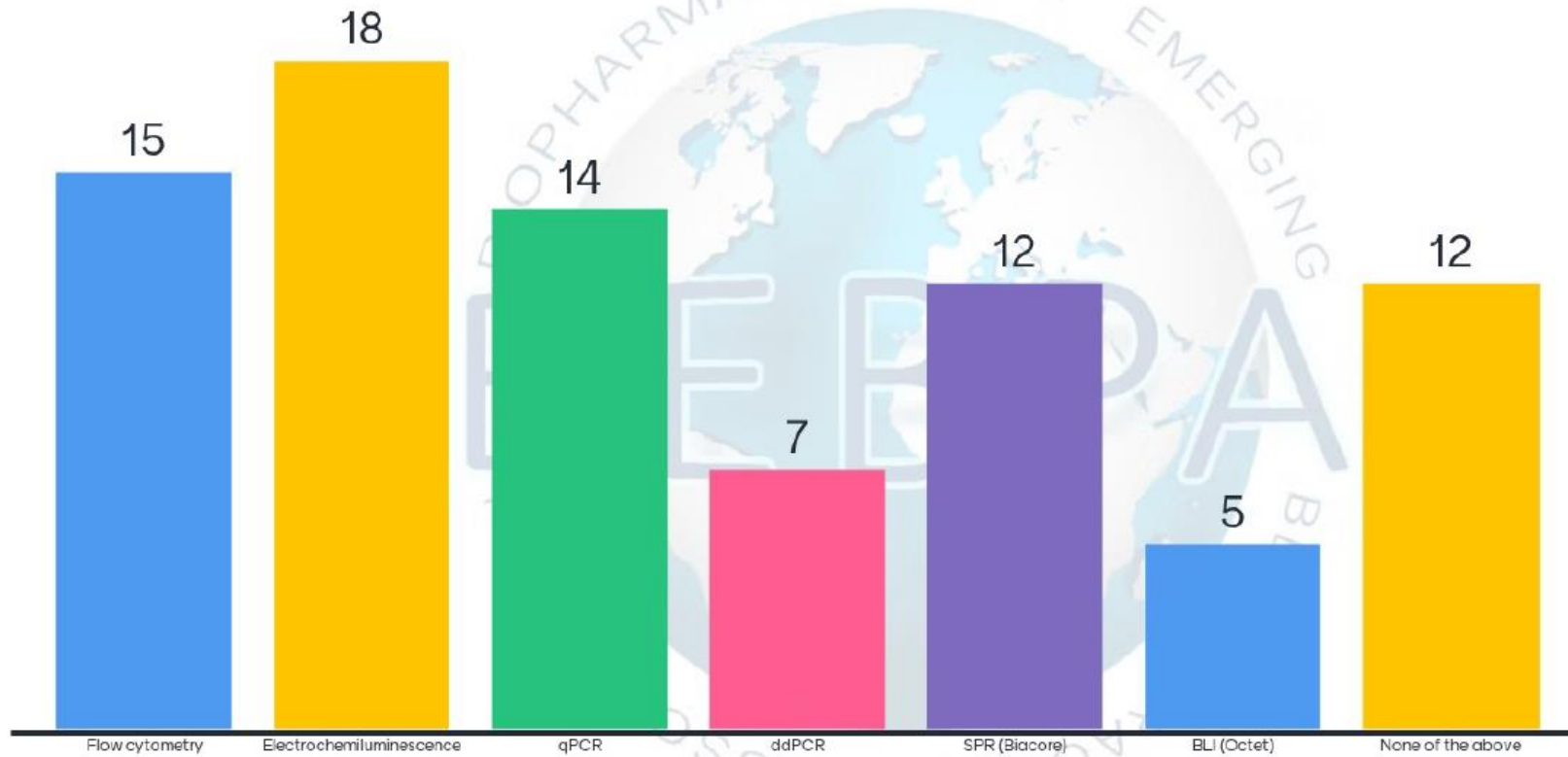
# 1.9 If you automate your assays: what level of automation do you use?



1.10 Do you use in-house or commercial software for calculation of the reportable value? Write the name of the software you typically use.



# 1.11 What kind of readouts do you use for your bioassays apart from absorbance/luminescence/fluorescence?

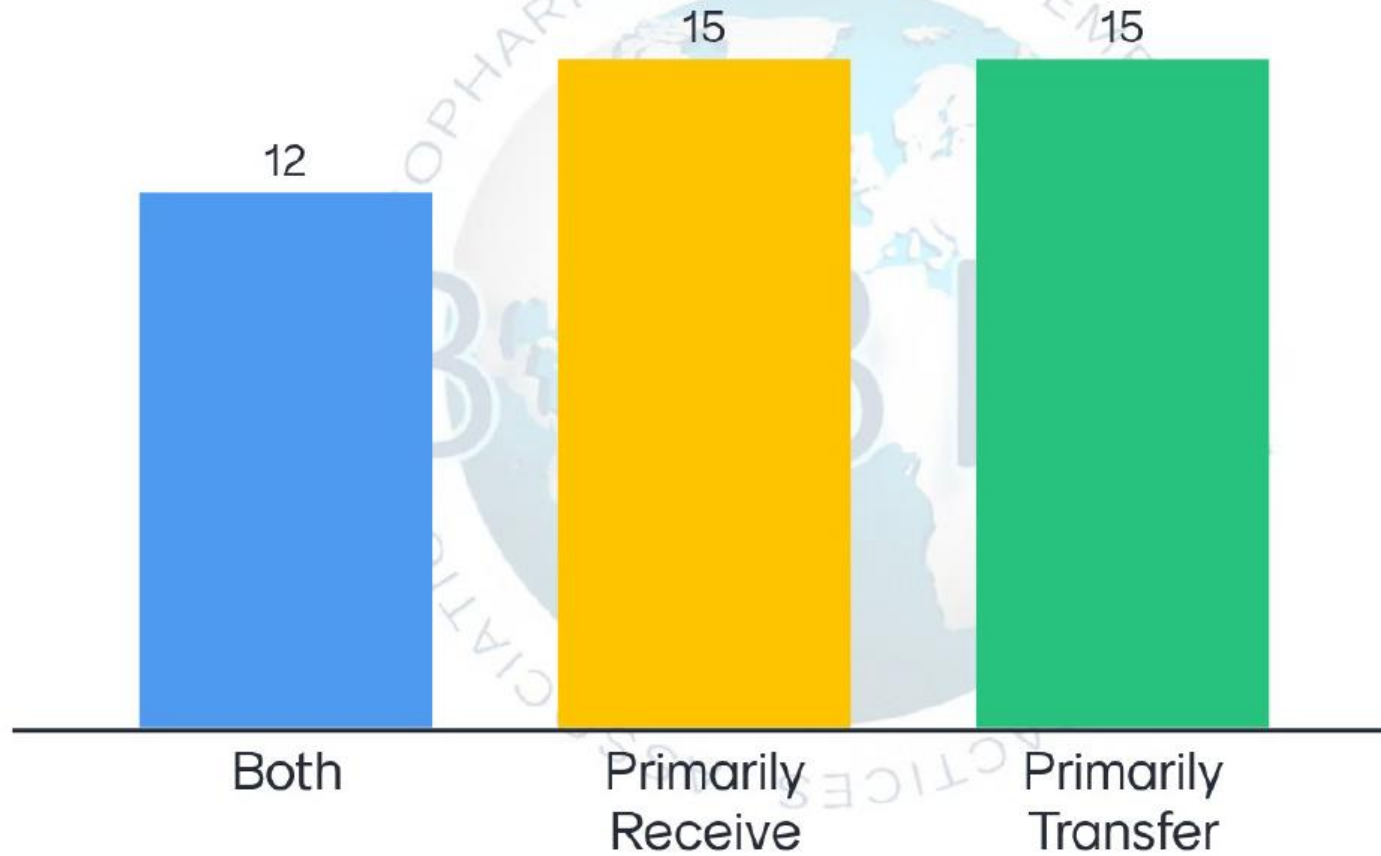


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# Section 2a: Transfer Questions



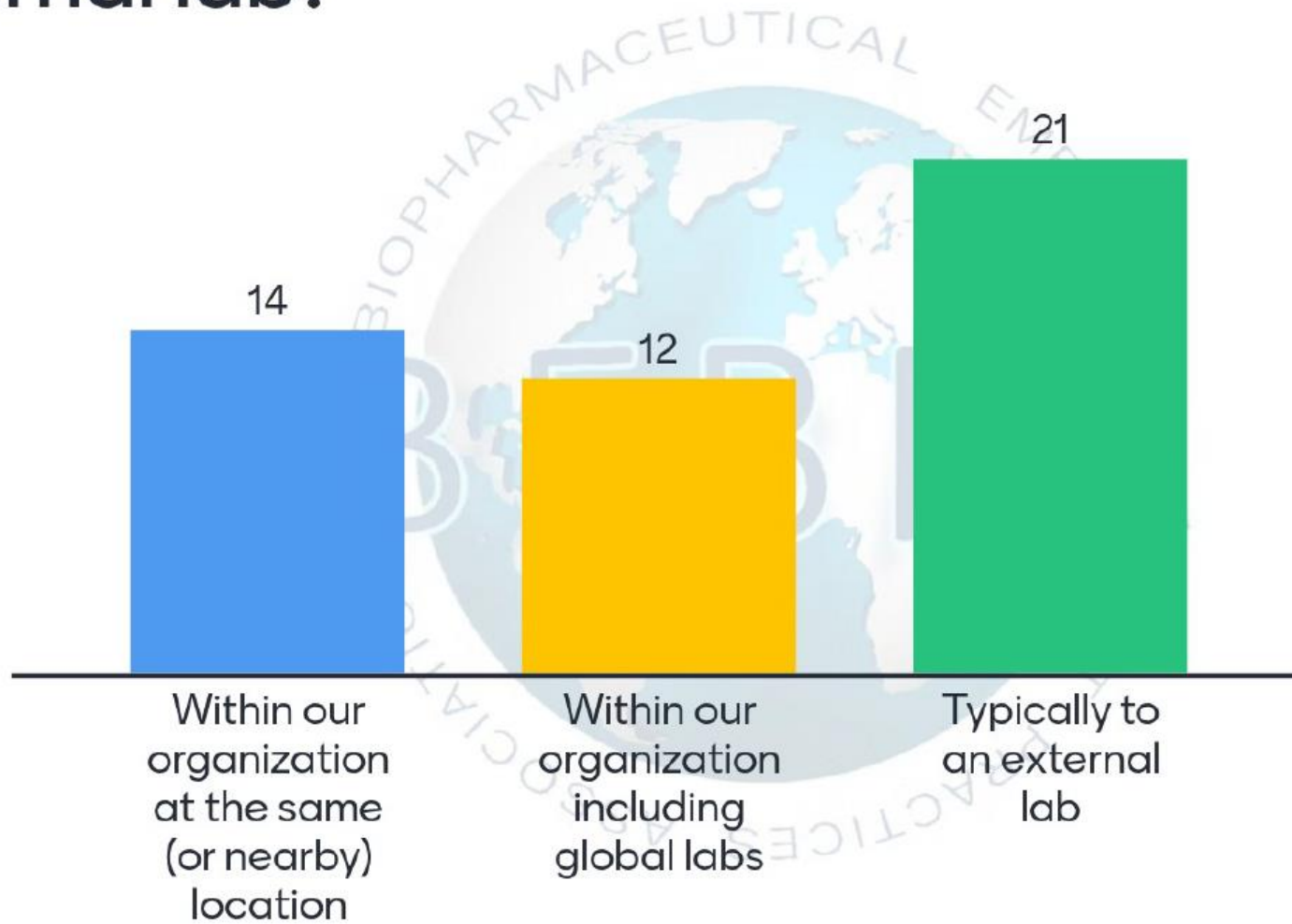
## 2.1 Are you typically the receiving or the donor laboratory?



## 2.2 How many transfers are you involved with per year?



## 2.3 Do you typically transfer within your organization or to an external lab?



## 2.4 Do you apply the concept of co-validation instead of assay validation at sending lab followed by assay transfer to receiving lab?

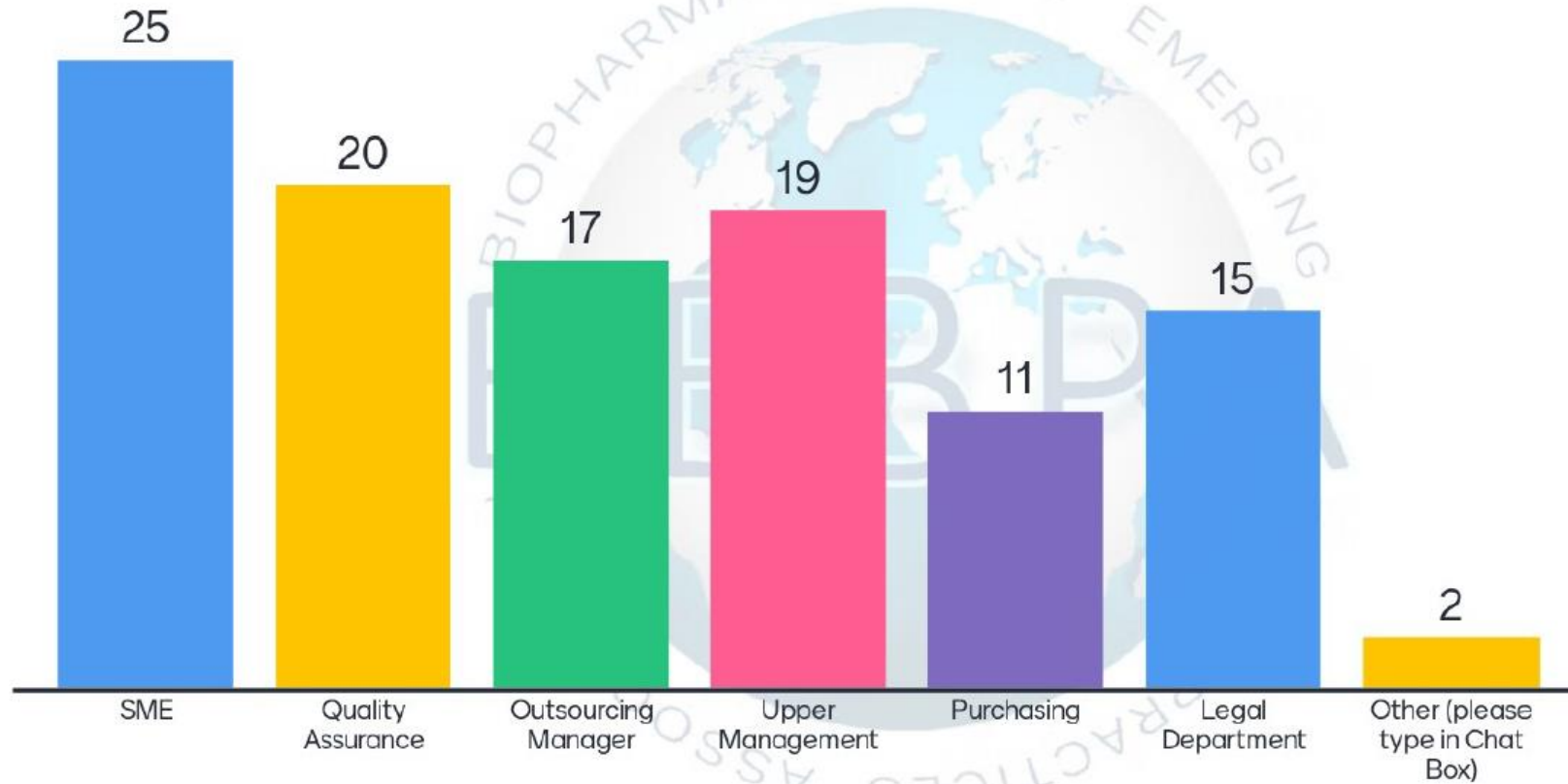


# Section 2b: Selecting the Lab



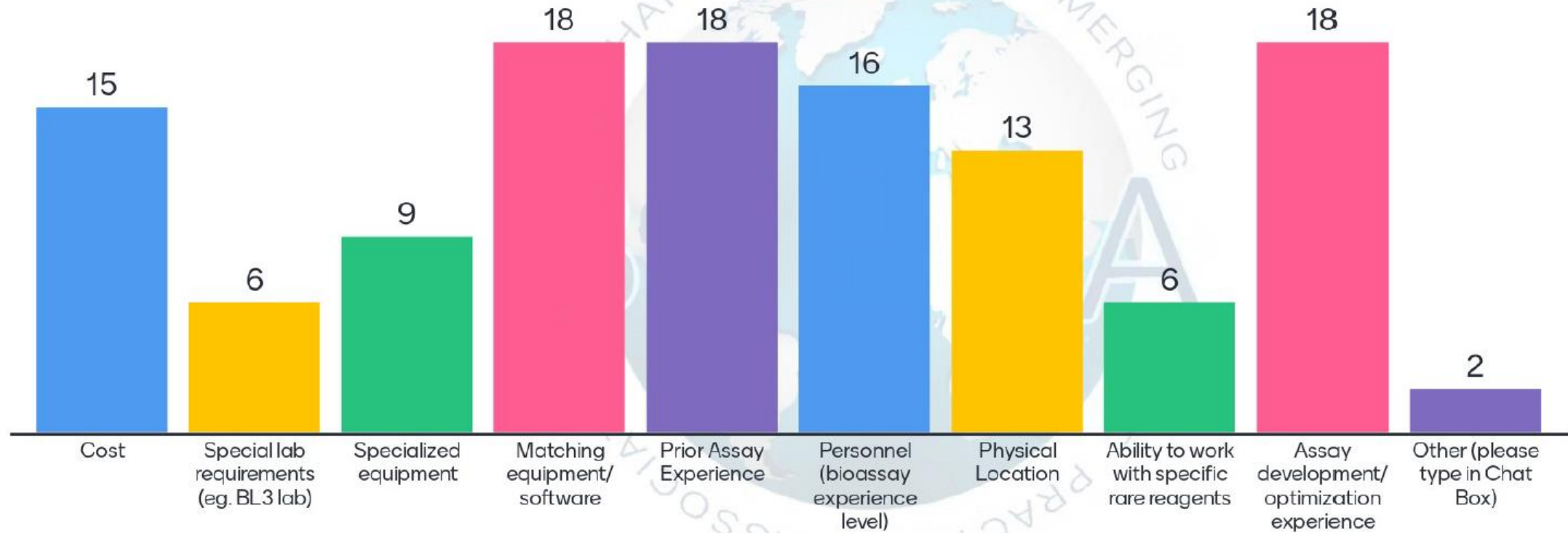


## 2.5 Who is included from your team when selecting an external lab? (Check all that apply)





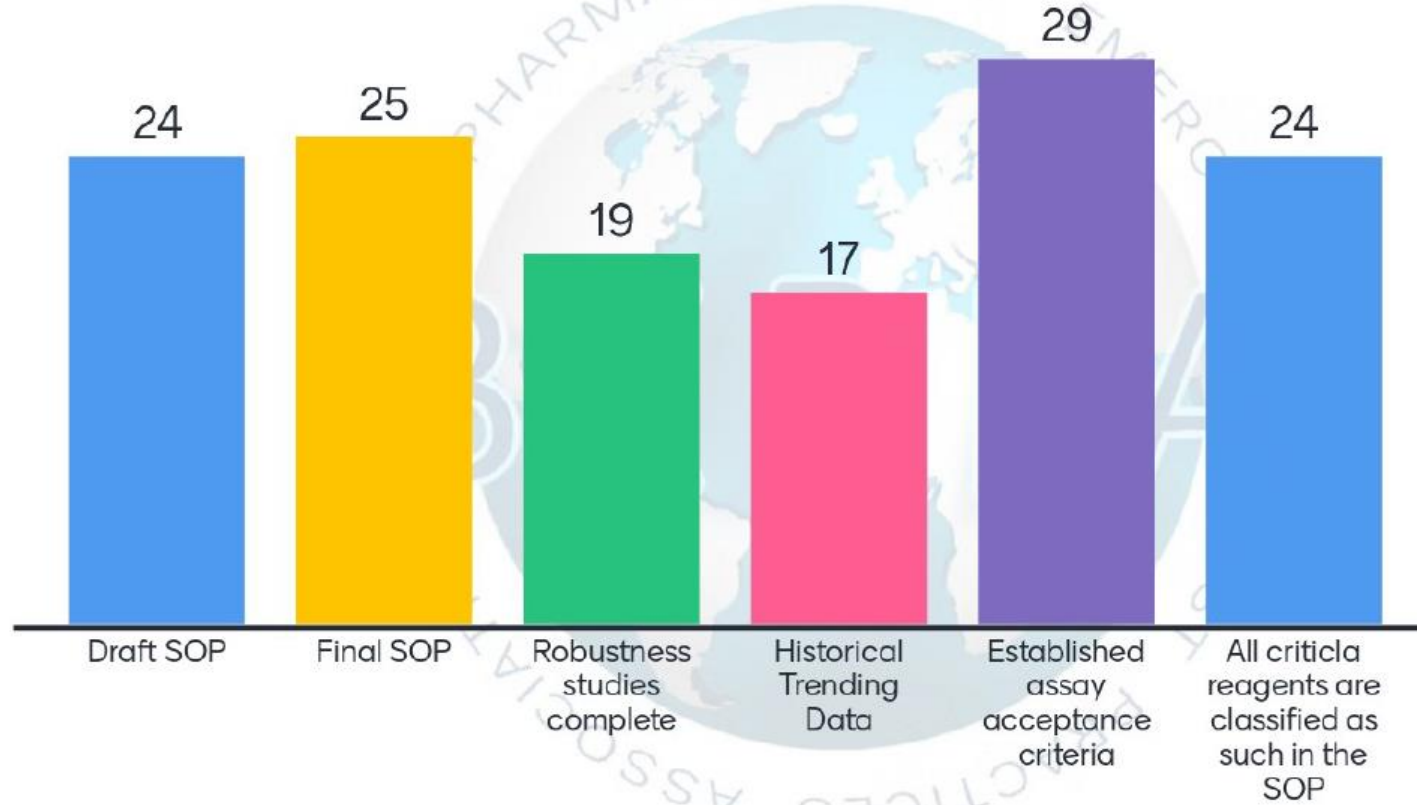
## 2.6 What are the top three criteria for selection?



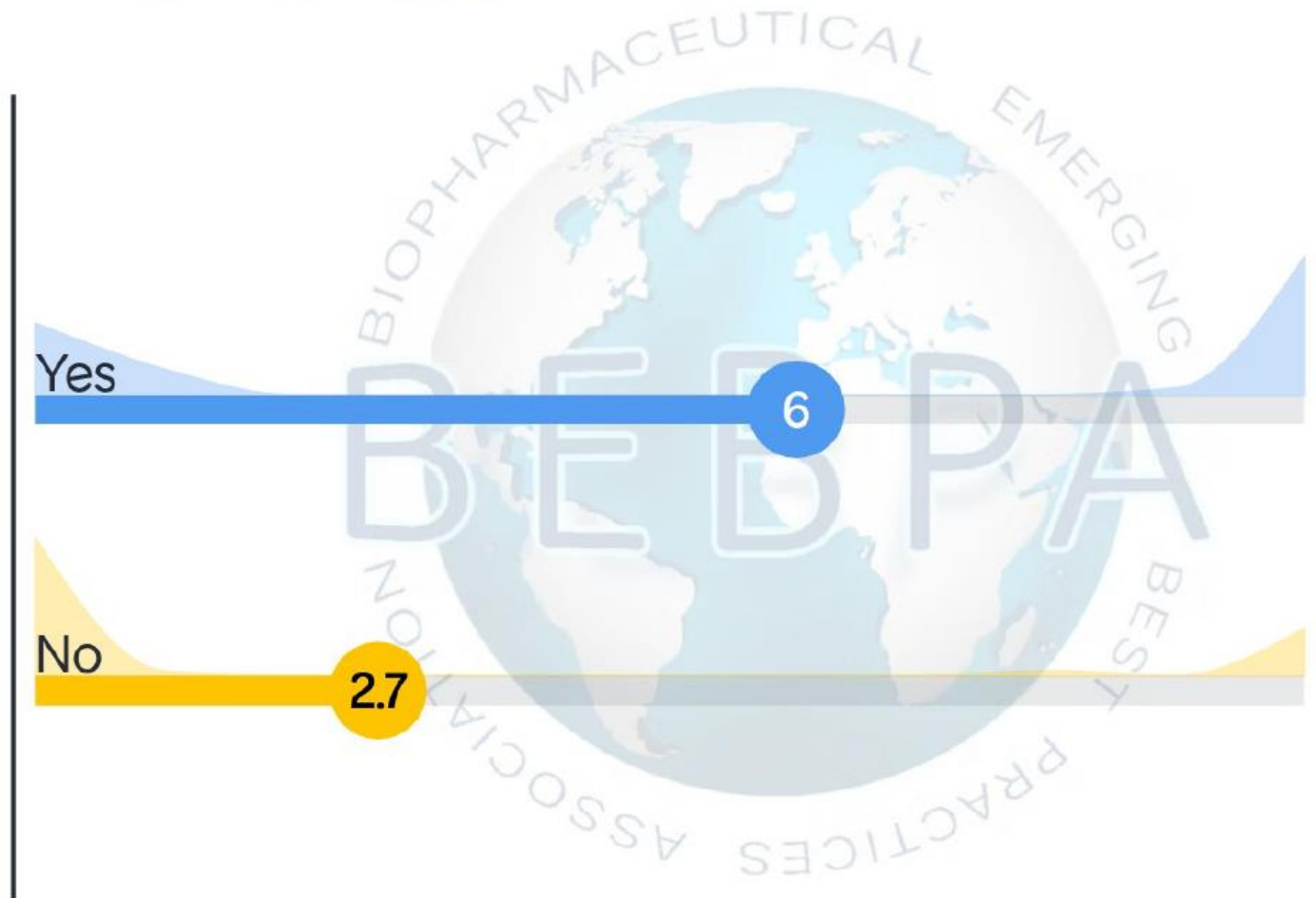
A large, faint watermark of the BEBPA logo is centered in the background. It consists of a globe with the text 'BIOPHARMACEUTICAL EMERGING MARKETS' at the top and 'BEST PRACTICES ASSOCIATION' at the bottom, with 'BEBPA' in the center.

# Section 3: Assay Basics- Pre-transfer Activities and checklists

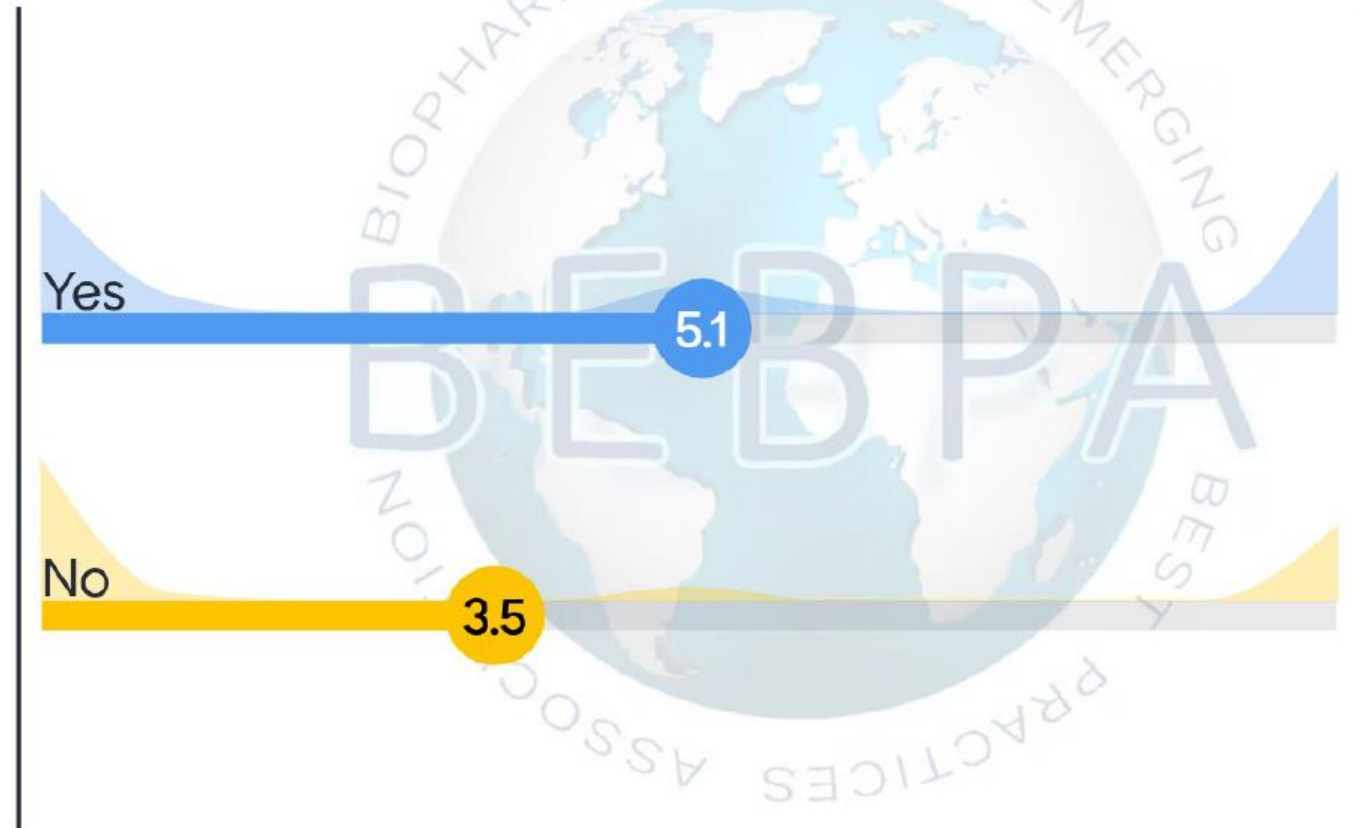
### 3.1 When you transfer an assay what information do you usually have available? Choose all that apply.



### 3.2 Do you have a transfer SOP for transferring method to external and/or internal labs?

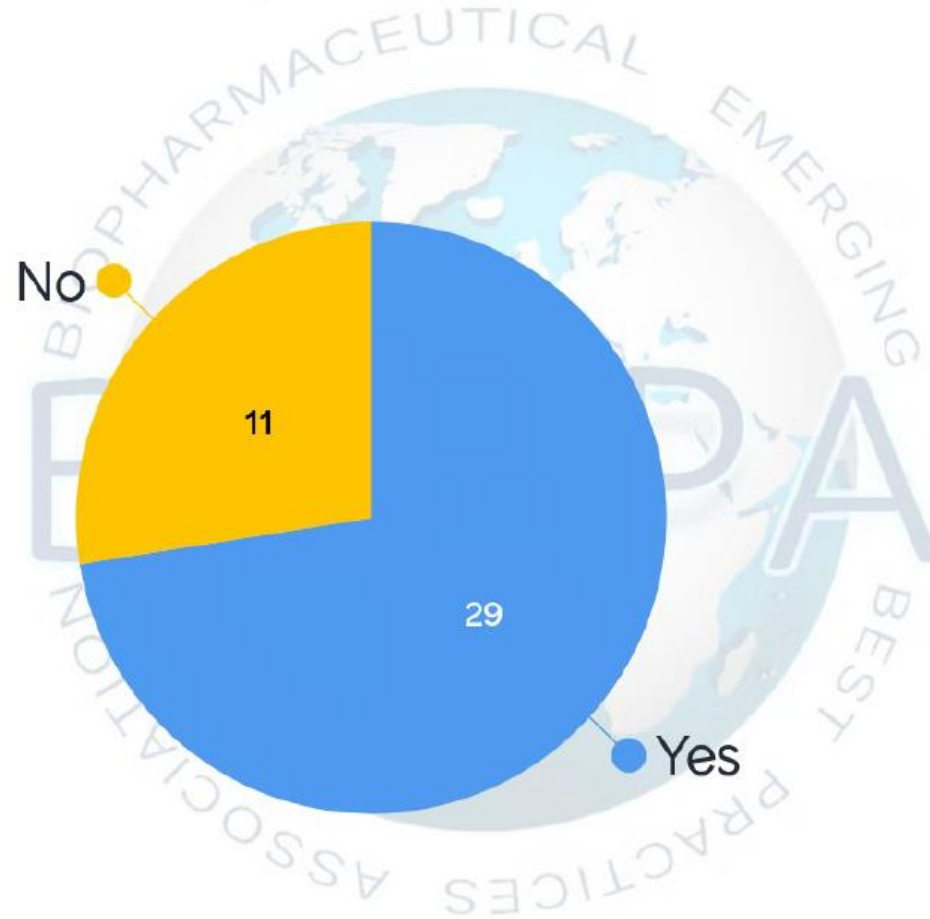


### 3.3 Do you include QA advice prior to approaching receiving lab?



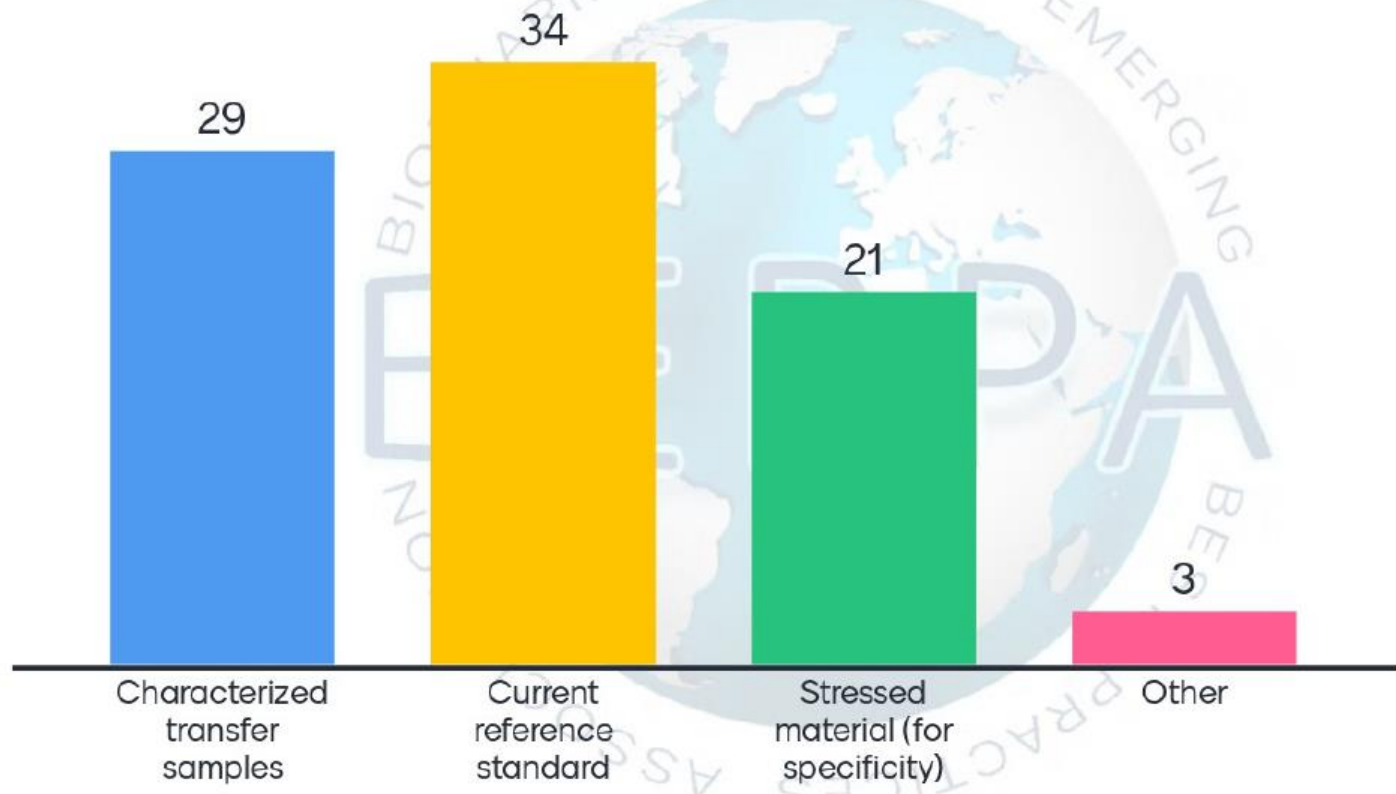


### 3.4 Do you provide all critical reagents or request that the receiving lab provide them (e.g. cells, ligands)?

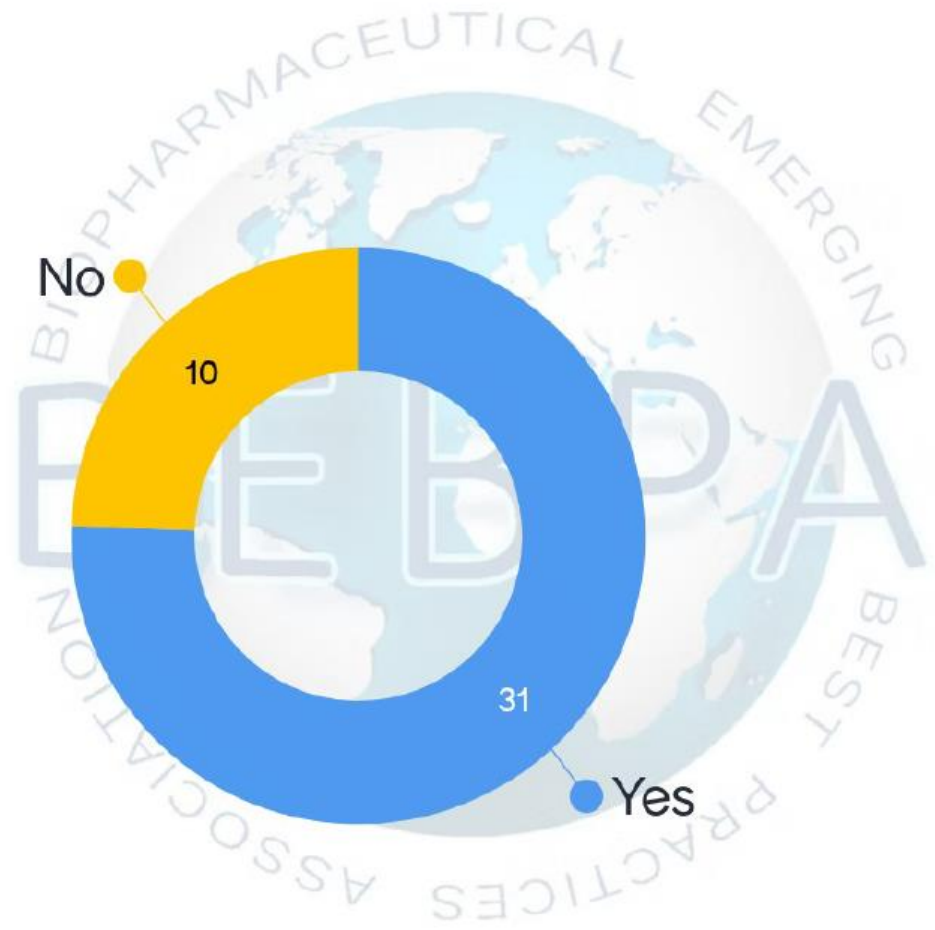




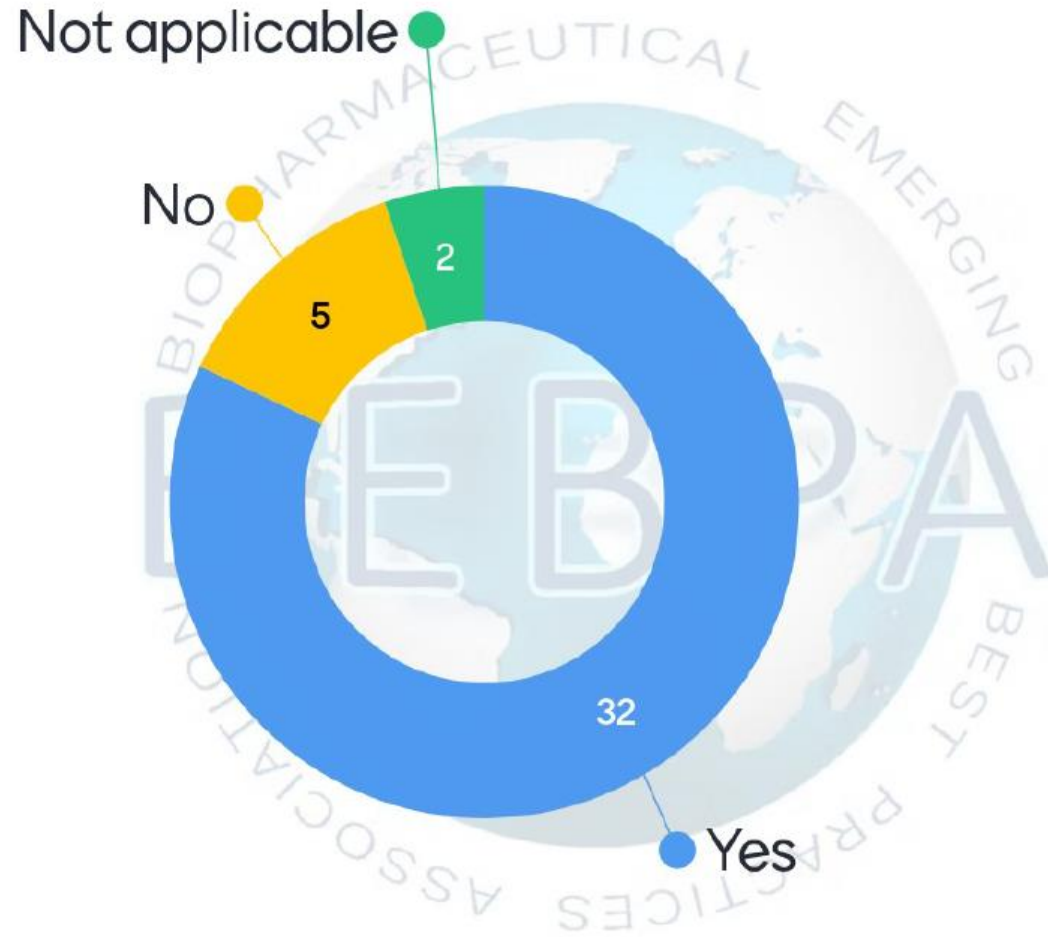
# 3.5 What kind of samples would you use for transfer? (Check all that apply)



# 3.6 Do you have a standard training requirement prior to transfer?



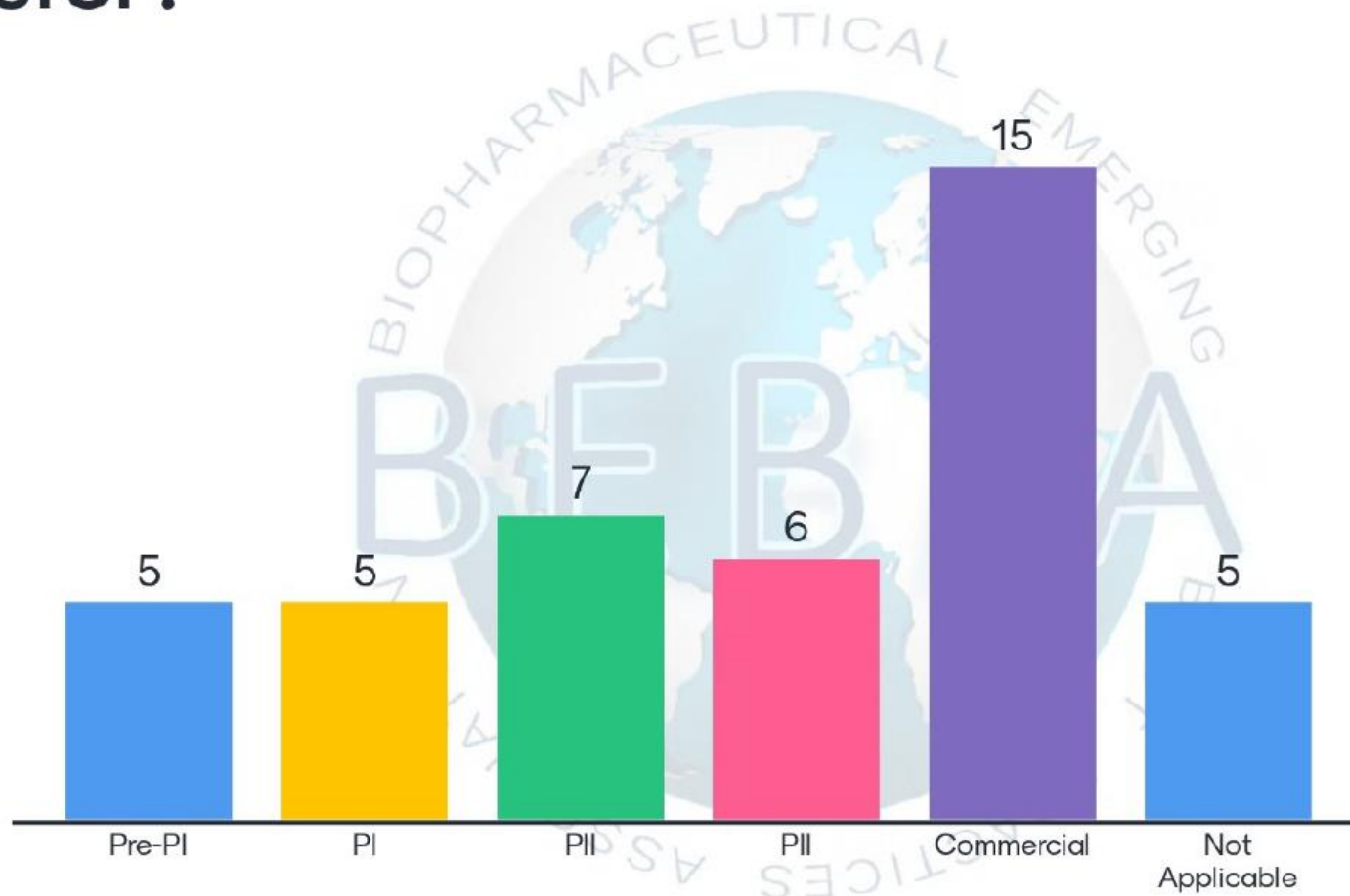
# 3.7 Do you perform a gap Analysis?



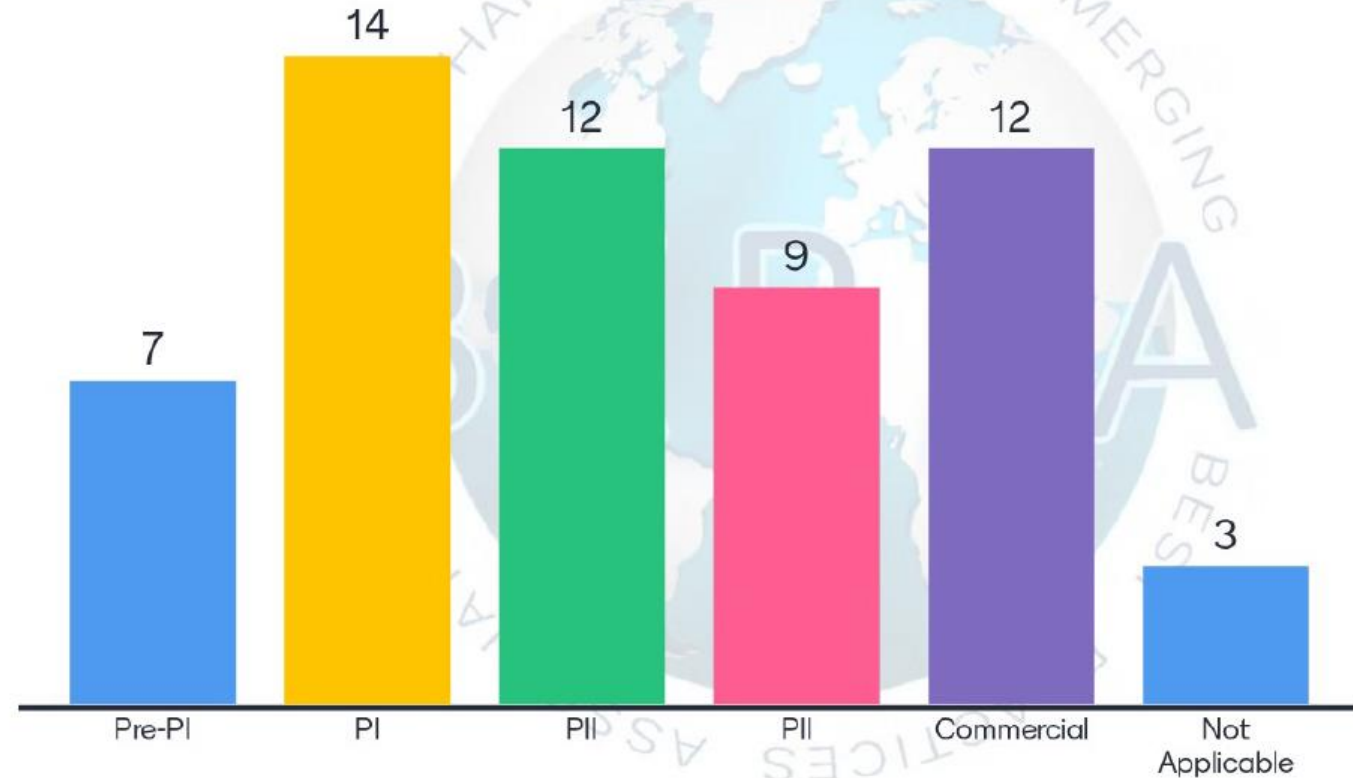
# Section 4: Stage Appropriate Transfer



# 4.1 What is the current phase of your project you want to transfer?

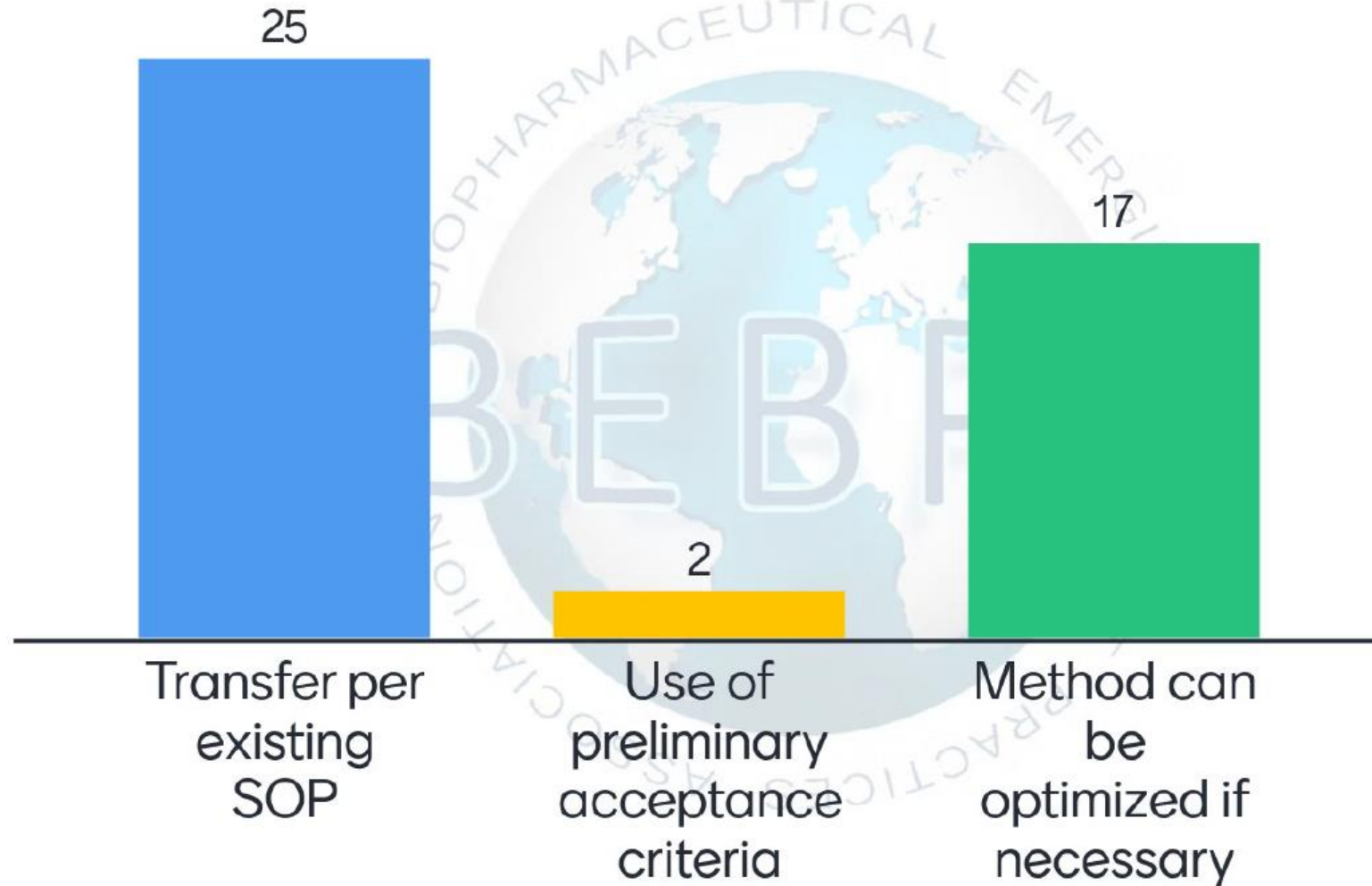


# 4.2 At what phase do you typically transfer your assays?





## 4.3 What is generally the scope of the transfer?



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**Thank You For Answering These Questions!**

